Performance Inspection Procedure

The Performance Inspection Procedure (PIP) is designed to be a closed-case acceptance test of the defibrillator prior to placing the device into service. The PIP should always to performed at the completion of the Test & Calibration Procedure (TCP). The PIP can also be used for customer initial product acceptance or during preventive maintenance checks. This servicing document describes the inspection tests you will perform to determine if the LIFEPAK 1000 defibrillator is operating within required specifications.

The **PIP Checklist** is provided as an optional tool for recording test results.

The Performance Inspection Procedure (PIP) shall be performed by authorized technically knowledgeable **Personnel** or Physio-Control service representatives.

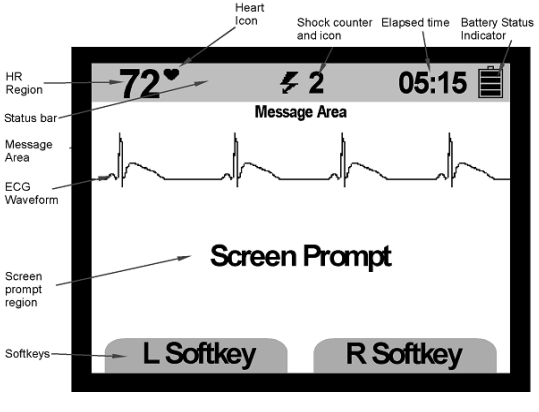
The device, as described within this servicing document, is supported by a warranty. For malfunctions encountered during use or inspection, contact Physio-Control. In the USA, contact Physio-Control Technical Services at 1.800.442.1142 and select option 5 for service. Outside the USA, contact your local Physio-Control representative.

This inspection consists of safety and performance tests recommended by AHA/ASHE (American Hospital Association/American Society for Hospital Engineering) Maintenance Management for Medical Equipment and International Electrotechnical Commission (IEC) Technical Report 1288-2, Maintenance of Cardiac Defibrillators-Monitors.

PIP – Scope and Applicability

This PIP applies to the LIFEPAK 1000 defibrillator exclusively. The PIP is written to be performed from end-to-end, meaning that the end of one test flows into the start of the next test. This flow is designed to reduce PIP test time. All PIP tests applicable to the LIFEPAK 1000 defibrillator configuration under test must be performed.

PIP – Device Layout



Note: Throughout the body of this PIP, the LIFEPAK 1000 defibrillator is referred to as the device.

Refer to the **PIP – Resource Requirements** for a listing of the necessary qualifications for PIP equipment, test equipment verification, workstation power, and personnel.

Refer to the **PIP – Test Equipment Requirements** for a listing of test equipment, including specifications, required to complete the PIP.

Perform the complete PIP as part of a regularly scheduled preventive maintenance routine. Also, perform the PIP after any test & calibration procedure.

PIP – Resource Requirements

This section describes the requirements for PIP equipment, PIP test equipment verification, PIP workstation power, and PIP personnel qualifications.

PIP – Equipment

To perform the PIP, use the equipment listed in the **PIP – Test Equipment Requirements** table. Although the table lists specific test equipment by manufacturer, test equipment with equivalent specifications may be substituted.

PIP – Test Equipment Verification

All test equipment used to perform the PIP must have a current calibration label. The calibration label must be issued by a certified calibration facility.

PIP – Workstation Power

If ac power if required for testing, the ac line power to the workstation must be connected to a grounded power source.

PIP – Personnel

Personnel who perform the PIP must be familiar with the operation of the LIFEPAK 1000 defibrillator and must meet at least one of the following requirements (or the equivalent):

- *Associate of Applied Science, with an emphasis in biomedical electronics*
- *Certificate of Technical Training, with an emphasis in biomedical electronics*
- *Equivalent biomedical electronics experience*

PIP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
Defibrillator Analyzer	**Output Power Measurement:** - Load resistance: 50 Ω ±1%non -inductive 160 W. - Range: 1000 J: 0-1000.0 J;100 J: 0-100.0J - Resolution: 0.1J - Accuracy: 1000 J Range: ± 2% of reading; 100 -1000 J: +/-2J 100 J Range: ± 2% of reading +/-0.1J **ECG Waveforms:** QRS complex: Rates: 120 BPM Rate Accuracy: +/-1% of setting. Amplitude: Fixed at 1mV Lead II (RA-LL); Fixed at 1.1 mV (Apex-Sternum) Amplitude Accuracy: ± 10% (Apex-Sternum),± 2% (RA -LL)	FLUKE QED-6 or equivalent*

PIP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
Defibrillator Analyzer (continued)	**Performance Waveforms:** Sine Waves: 10Hz Time Base Accuracy: +/-1% of setting. Amplitude: Fixed at 1mV Lead II (RA-LL); Fixed at 1.1 mV (Apex-Sternum) Amplitude Accuracy: ± 10% (Apex-Sternum),± 2% (RA -LL)	
Assembly Battery, Primary, 5/4C Cell, LIMNO2, LIFEPAK 1000		Physio-Control - p/n 3205379-002
Cable Assembly, Fast Patch, LIFEPAK 500		Physio-Control - p/n 3010493-004,-005
Timer (Stop-Watch)	1 -second resolution	Commercial
Graticule	1 mm resolution +/-2%	Commercial, Vipcharts.com, p/n LP1000

PIP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
Digital Multimeter (DMM)	Range: 400 Ω. Accuracy: +/-(0.2%+2)	Fluke 87or equivalent*
Decade Resistance Box	Range: 0-500 Ω, Resolution: 1 Ω Accuracy:+/- 1%	IET Model RS-200 or equivalent*
Safety Analyzer	110 or 220 Vac line voltage Current range: 0-1999 µA Current accuracy: +/-5% of reading +/-1 digit	Dale Model 600/600E, 601/601E or equivalent*
Electrode test Post Adapter (2 each)		Physio-Control - p/n 3205979-000
Cable Assembly, 3 wire ECG, LIFEPAK1000		Physio-Control - p/n 3204273-002, -003
Cable, Quick-Combo to ECG Snap Termination		Physio-Control - p/n 3009139-001

*Equivalent equipment is required to meet the specifications listed in the specifications column.

PIP - Checklist

Recording Device Configuration on PIP Checklist

The **PIP Checklist** is provided as an optional tool for recording test results.

The **Device Configuration Table** is provided to decipher the 20-digit Device Configuration number listed on the DEVICE DATA screen, which can be accessed in the **SETUP**/GENERAL submenu. The PIP Checklist provides space to record this number before beginning the Performance Inspection Procedure (PIP).

Capturing the Device Configuration number on the checklist prior to PIP provides a way for the operator to confirm device setup options weren't unintentionally changed during PIP testing.

Refer to LIFEPAK 1000 Operating Instructions 3205213 for Device Setup Option information.

PIP – Instructions

PIP - General Instructions

This section lists the general instructions for performing the Performance Inspection Procedure (PIP).

- All PIP tests applicable to the LIFEPAK 1000 Defibrillator configuration under test must be performed.
- See the Troubleshooting section of the Service Manual to correct failures and Service Log diagnostic codes 4000 and above, then repeat the PIP.

Note: All diagnostic codes below 4000 are informational and can be cleared.

- (Optional) Record device configuration on PIP Checklist prior to start of PIP procedure.
- Repeat the PIP after the TCP.

PIP - Entering Setup Mode

1. Hold down **L SOFT KEY** and **R SOFT KEY** controls and press **ON** (green) button on the device. Hold the controls until SETUP or SETUP MODE PASSWORD menu appears.

Note: For device software version 2.2 or greater with **CONFIG A** enabled, follow the on-screen directions and enter the 4 digit password (default is 0000) to enter SETUP MODE.

PIP - Entering Service Mode

2. Press the **NEXT** key until SERVICE MODE is highlighted.
3. Select **SERVICE MODE** from the Setup menu.
4. Select **YES** to enter SERVICE MODE - PASSWORD screen.
5. Follow the on screen directions and enter the 4 digit password (0000 default or 5433) to enter SERVICE MODE.

Note: While entering Service Mode, if you wait longer than 5 seconds to make an entry, the screen will revert to the Setup screen. In this case restart from step 2.

PIP – Instructions

PIP – Physical Inspection

Perform the exterior physical inspection as described.

1. Remove device from softcase. (if applicable)
2. Inspect all exterior surfaces of the device for damage.
3. Lift and turn over the device and listen for loose or rattling internal hardware. If loose hardware is suspected, investigate and correct or contact Physio-Control before performing this procedure.
4. Inspect the case for separation (integrity of case seal).
5. Check for bent, broken, or corroded therapy connector sockets or therapy cable pins. Clean or replace damaged components as required.
6. Check date sensitive materials (electrodes, batteries) to ensure they have not exceeded their shelf life date.

Note: Whenever possible, use the customer owned cables and accessories when performing the PIP.

Note: Damage to softcase or date sensitive materials exceeding shelf life are not reasons for failing the PIP.

PIP – Instructions

1 - Battery Installation Test

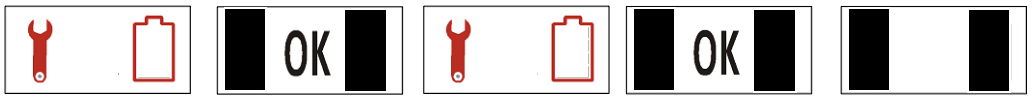
Readiness Indicator

OK INDICATOR

SERVICE INDICATOR (active)

BATTERY CAPACITY INDICATOR

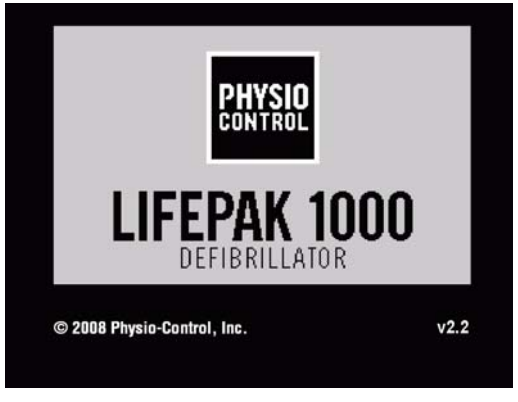
1. Verify no battery installed into the device, no electrodes connected to the device.
2. Wait 60 seconds before installing the battery into the device.
3. Install battery into the device. Verify the device completes a brief power initialization cycle, which includes the following:
   - The Readiness Indicator graphics toggle from a unpowered state to the final powered state as shown below:



   - Momentarily flashes the ON and SHOCK button LEDs
   - The LCD display backlight is lit
   - The Initalization Display Screen is displayed on LCD
4. After initalization is complete, verify the device turns itself OFF.
   - Verify the **BATTERY CAPACITY INDICATOR** shows one segment or greater.
   - Verify the **SERVICE INDICATOR** is OFF (covered by black rectangle)
   - Verify The **OK INDICATOR** is ON.

PIP – Instructions

2 - Power Up Initialization Test

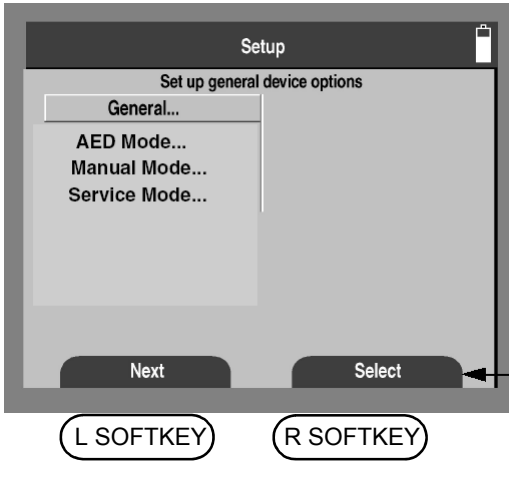


Initalization Display Screen

1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service Indicator is OFF, OK Indicator is ON.
2. Turn the device ON to initiate the device initialization self- test.
   - Verify the **OK INDICATOR** flash momentarily ON and back OFF
   - Verify the **SHOCK** LEDs flash momentarily ON and back OFF.
   - Verify **ON** indicator glows steadily while device is on.
   - Verify the LCD display does not show “Replace Battery message”.
3. Verify the Voice prompt is heard “Connect Electrodes”.
4. Turn the device OFF.

PIP – Instructions

3 - Service Alert test / Audio-Voice prompt tests



1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF, OK indicator is ON
2. Hold down **L SOFT KEY** and **R SOFT KEY** controls and press ON (green) button on the device. Hold the controls until SETUP or SETUP MODE PASSWORD menu appears.

Note: For device software version 2.2 or greater with **CONFIG A** enabled, follow the on-screen directions and enter the 4 digit password (default is 0000) to enter SETUP MODE.

3. Select **GENERAL** from the Setup menu. Select **AUDIO** from the Setup/General menu.
4. Select **SERVICE ALERT** from the Setup/General/ Audio menu.
5. Select Service Alert **ON**.
6. Verify that several audio beeps are clearly audible.

Note: As required, reset the Service Alert to the customer original setting.

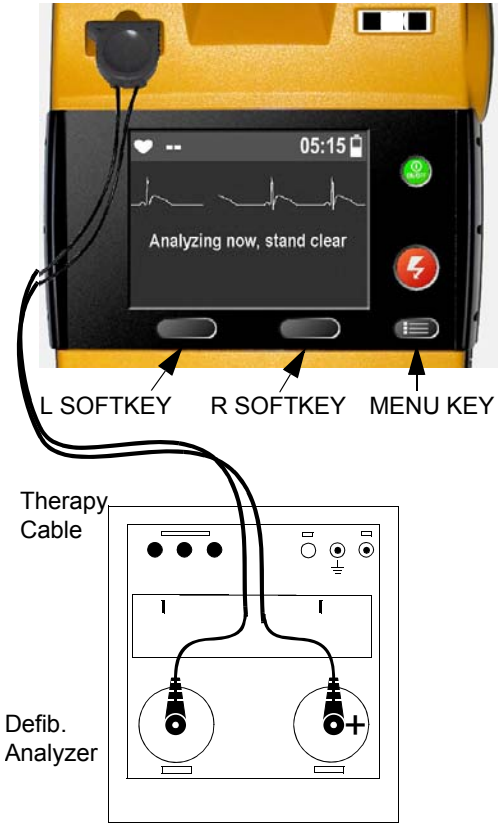
7. Select **PROMPT VOLUME** from the Setup/General/ Audio menu.
8. Verify that the Prompt Volume is set to HIGH**.** If not already set, select Prompt Volume to **HIGH**.
9. Turn the device OFF then ON, and verify the sound prompt produced by device has no audible distortion.

Note: As required, reset the Prompt Volume to the customer original setting.

10. Turn the device OFF.

PIP – Instructions

4 - Defibrillator Energy Output /Charge Time / Buttons and Keys test / Defibrillator Energy Dump test.



1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF, OK indicator is ON.
2. This test will exercise all keys, verify that all control keys on the device are functioning properly during performance of this test.
3. Place the device into SETUP/ **SERVICE MODE.** See “Entering Service Mode”.
4. Connect the therapy cable into the Defibrillator Analyzer.
5. Set the Defibrillator Analyzer to the highest joule scale setting, select Energy.
6. Select **DEFIB CAL** from the on-screen SERVICE menu to access the SERVICE/DEFIB CAL Sub-Menu.
7. Select START on the device to initiate the first calibration energy level (100J).
8. Press the flashing **SHOCK** button to discharge the device as soon as it is fully charged.
9. Verify that the Defibrillator Analyzer indicates the delivered energy at 100J is within 95J and 105J. Perform the **TCP-Energy Calibration** if the delivered energy falls outside of the acceptable output range.
10. Press **Menu key** four times to retain the current calibration value if the delivered energy falls within the acceptable output range.

WARNING

Do not touch the **Increase** or **Decrease** buttons on the device during the verification. Failure to do so may lead to the device energy miscalculations.

PIP – Instructions

4 - Defibrillator Energy Output / Charge Time / Buttons and Keys test / Defibrillator Energy Dump test (continued).

11. Press **OK** and start Stopwatch simultaneously (use Stopwatch for first 360 J charge time).The device will proceed to the next calibration level (360 J).
12. Stop the Stopwatch as soon as the device's SHOCK button starts to flash.
13. Verify that the device charged to 360J in 14 seconds or less.
14. Press the flashing **SHOCK** button to discharge the device.
15. Verify that the Defibrillator Analyzer indicates the delivered energy at 360J is within 342J and 378J. Perform the **TCP-Energy Calibration** if the delivered energy falls outside of the acceptable output range.

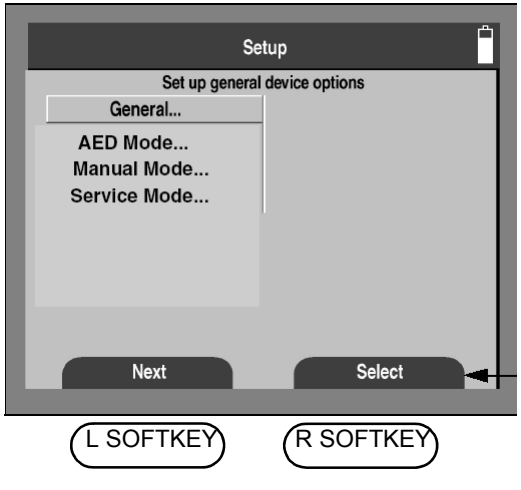
WARNING

Do not touch the **Increase** or **Decrease** buttons on the device during the verification. Failure to do so may lead to the device energy miscalculations.

16. Press **Menu key** four times to retain the current calibration value if the delivered energy falls within the acceptable output range. Press **OK**.
17. Repeat steps 6 through15 to verify 100J and 360J Defibrillator Energy Outputs for a second time are within the acceptable output limits**.**
18. This time repeat steps 6,7,9, and 10 (without stopwatch)**.**
19. When full 360 J charge is reached, turn the device OFF and then turn the device back ON.
20. Verify Energy dump test doesn't result in service wrench (Service indicator is OFF).
21. Turn the device OFF.

PIP – Instructions

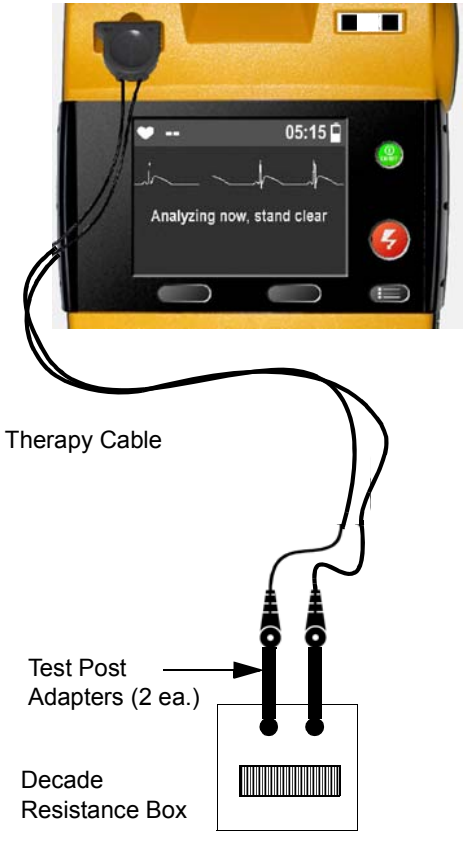
5 - Date & Time / Contrast / Full Monthly Auto test



1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF, OK indicator is ON.
2. Place the device into **SETUP MODE**. See “Entering Setup Mode”.
3. Select **GENERAL** from the Setup menu.
4. Verify that the **Date/Time is correct and contrast of characters displayed on LCD are legible** from the Setup/General.
5. Select **DATE/TIME** from the Setup/General menu.
6. Set Date to the first Monday of the month.
7. Set Time to 02:59.
8. Immediately turn the device off. Then observe the device performing Full (Monthly) Auto test at 03:00.
9. Wait for 80 seconds; look for the power ON LED and SHOCK button to blink.
10. Verify OK returns to the Readiness Indicator.
11. Reset Date and Time in device to correct local date and time from the Setup/General/ Date/Time menu.
12. Place the device into SETUP/ **SERVICE MODE.** See “Entering Service Mode”.
13. Verify no diagnostic codes (codes below 4000 are allowed) in the Setup/Service mode/ Service Log menu. See **PIP - General Instructions**
14. Turn the device OFF.

PIP – Instructions

6 - Electrode Impedance test



1. Verify Battery Pak is installed into the device. Therapy cable is connected to the device. Service indicator is OFF, OK indicator is ON.
2. Connect the Therapy Cable to the Decade Resistance Box.
3. Set the Decade Resistance box to 355 Ω
4. Using DMM to verify the Decade Resistance box is 355Ω+/–5 Ω.
5. Turn the device ON. Verify that the device voice prompts:

- ***CONNECT ELECTRODES***

Note: Actual voice prompts will vary depending on the device configuration.

Note: Do not discharge device into the Decade Resistance Box.

6. Set the Decade Resistance Box to 246 Ω .
7. Using DMM to verify the Decade Resistance box is 246 Ω +/–4 Ω.
8. Verify that the device voice prompts:

- ***STAND CLEAR OR PUSH ANALYZE***

9. Set the Decade Resistance Box to 5 Ω .
10. Using DMM to verify the Decade Resistance box is 5 Ω +/–0.2 Ω.
11. Verify that the device voice prompts:

- ***CONNECT ELECTRODES.***

12. Turn the device OFF.

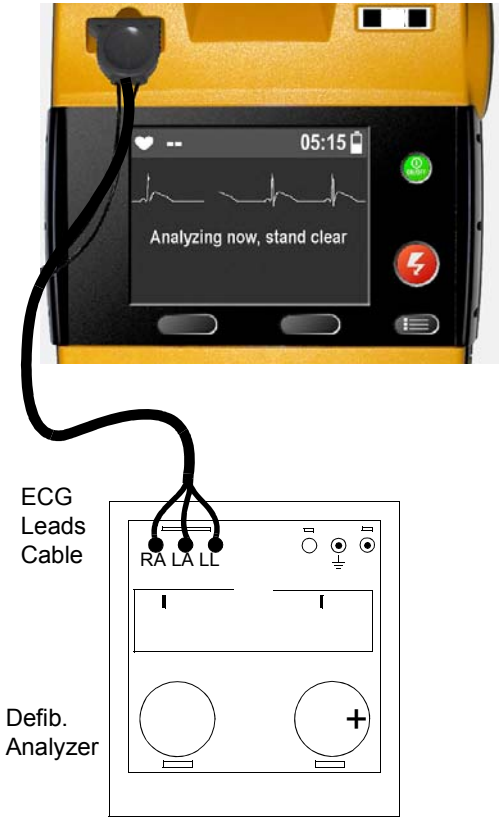
PIP – Instructions

7 - Warm Boot Detection Test

1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF, OK indicator is ON.
2. Turn the device ON.
3. Verify Readiness Indicator OK and Wrench are displayed momentarily.
4. Verify Readiness Indicator display updates as shown.
5. Note the current count on the elapse timer, found at top of LCD display.
6. Turn the device OFF.
7. Turn the device ON between 5 - 49 seconds after device shutdown.
8. Verify that the device returns to normal ON operation and the elapse timer has continued to increment counter during the device shutdown period (The device does not restart time count from 00:00).
9. Turn the device OFF.

PIP – Instructions

8 - ECG Leads Characteristic test



N/A - PIP Checklist test step if 3 Lead ECG feature isn't installed in device.

1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF, OK indicator is ON.
2. Turn the device ON.
3. Set the device to AED mode or verify the device is on AED mode.
4. Verify the device responds with a voice prompt: **"Connect electrodes"**
5. Connect the 3 lead ECG cable to the device.
6. Verify that the device displays "**ECG mode**" and "**Connect ECG leads**" message.
7. Connect the 3 lead ECG cable to Defibrillator Analyzer.
8. Verify that the device displays "**ECG mode**" message and a scrolling ECG trace.
9. Set Defibrillator Analyzer to 1mV, 10Hz Sinewave.
10. Use the graticule to measure the sine-wave amplitude* of 10 mm +/- 10% peak-to-peak on the LCD display.

Note*: The output of QED 6 is fixed at 1mV Lead II (RA-LL)

Note: If no ECG waveform is displayed, then device is configured with ECG Monitoring - Off.

11. Set Defibrillator Analyzer to ECG wave and 120 BPM.
12. Verify that the device displays the Heart Rate on LCD Display is within 117 to 123 BPM.
13. Remove RA lead from Defibrillator Analyzer.
14. Verify that the device displays "Connect ECG Leads" message within 1 second.

Note: Do not touch lead contacts with hand, this could interrupt leads off condition.

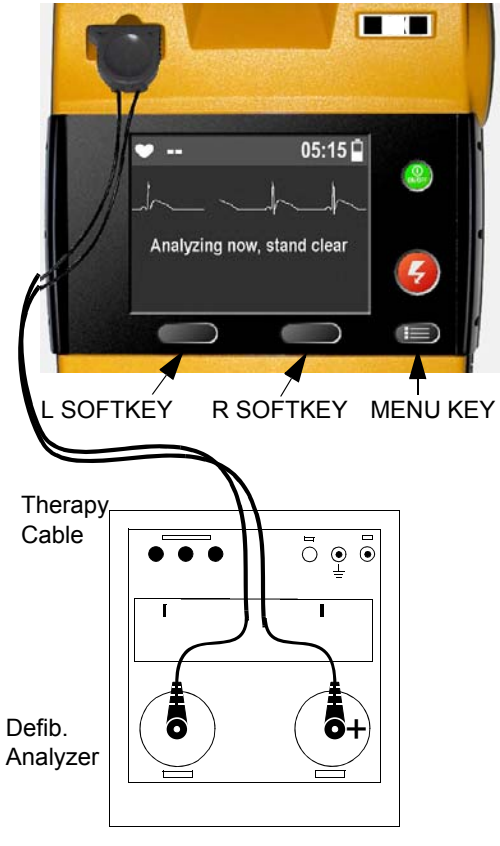
PIP – Instructions

8 - ECG Leads Characteristic test (continued)

15. Reconnect RA lead.
16. Repeat steps 13, 14 and 15 for the remaining LA and LL leads.
17. Disconnect 3 Lead ECG cable from device and Defibrillator Analyzer.
18. Turn device OFF.

PIP – Instructions

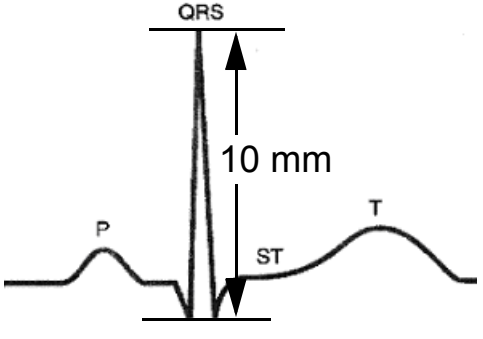
9 - Therapy ECG Characteristic test



1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF, OK indicator is ON
2. Set Defibrillator Analyzer to ECG Wave and 120 BPM.
3. Connect Therapy cable to device and Defibrillator Analyzer as shown.
4. Turn the device ON.
5. Use the graticule to measure the ECG R -wave amplitude* of 10 mm +/- 10% peak-to-peak on the LCD display

Note*: The output of QED 6 is fixed at 1.1 mV (Apex-Sternum)

Note: If no ECG waveform is displayed, then device may be configured with ECG Display - Off. Go to Setup/General/AED mode menu set ECG Display to ON. As required, reset the ECG Display to the customer original setting



6. Disconnect Therapy cable from device and Defibrillator Analyzer.
7. Turn the device OFF.

PIP – Instructions

10 - Leakage Current

Check to ensure the leakage current meets the following industry standards:

- AAMI/ANSI (Association for the Advancement of Medical Instrumentation/American National Standards Institute) DF2-1989, DF39-1993
- IEC (International Electrotechnical Commission) 601-1 and 601-2-4

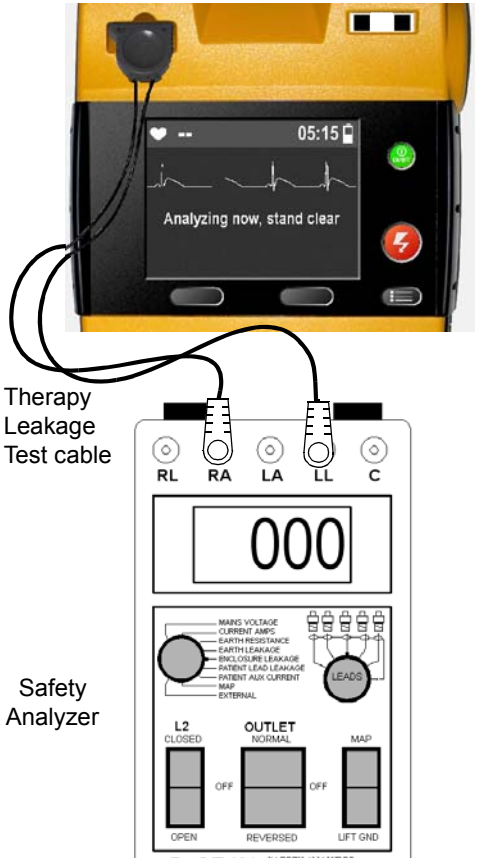
WARNING

Shock Hazard. Failure to properly perform these tests could result in a failure to detect excessive leakage current. Make sure you are familiar with your test equipment and these test performance procedures.

Note: Because of the variety of safety analyzers that may be used for these tests, this electronic service manual provides only general instructions. For information about configuration and testing methods, refer to your safety analyzer operating instructions.

PIP – Instructions

10a - Therapy Leakage Current



1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF, OK indicator is ON.
2. Connect the Quik-combo to ECG Snap Cable into the device.
3. Connect the **Apex/LL** of Quik-combo to ECG snap cable to the Safety Analyzer at LL snap.
4. Connect the **Sternum/RA** of Quik-combo to ECG snap cable to the Safety Analyzer at RA snap.
5. Set the Safety Analyzer Lead setting to RA or LL.
6. Turn the device ON.
7. Verify that the **Lead- Lead Leakage Current (RA-LL)** is between 1µA to 9 µA.
8. Remove the Quik-combo to ECG snap cable from the device and Safety Analyzer.

PIP – Instructions

10b- ECG Leads Leakage Current Test

N/A - PIP Checklist test step if 3 Lead ECG feature isn't installed in device.

1. Verify Battery Pak is installed into the device, no electrodes connected to the device and Service indicator is OFF.
2. Connect the 3 Lead ECG Test Cable into the device.
3. Connect the **LL Lead** of 3 Lead ECG Test Cable to the Safety Analyzer at LL snap.
4. Connect the **RA Lead** of 3 Lead ECG Test Cable to the Safety Analyzer at RA snap.
5. Set the Safety Analyzer Lead setting to RA or LL.
6. If off, turn the device ON.
7. Verify that the **Lead - Lead Leakage Current (RA - LL)** is between 0µA to 9 µA
8. Remove the **LL Lead** of 3 Lead ECG Test Cable from the Safety Analyzer.
9. Connect the **LA Lead** of 3 Lead ECG Test Cable to the Safety Analyzer at LA snap.
10. Set the Safety Analyzer Lead setting to RA or LA.
11. Verify that the **Lead - Lead Leakage Current (RA- LA)** is between 0µA to 9 µA.
12. Remove the **RA Lead** of 3 Lead ECG Test Cable from the Safety Analyzer.
13. Connect the **LL Lead** of 3 Lead ECG Test Cable to the Safety Analyzer at LL snap.
14. Set the Safety Analyzer Lead setting to LA or LL.
15. Verify that the **Lead - Lead Leakage Current (LA- LL)** is between 0µA to 9 µA.
16. Remove the 3 Lead ECG Test cable between the device and Safety Analyzer.
17. Turn the device OFF.

PIP – Device Configuration Table

Device Configuration

Use the following table to decipher the 20-digit Device Configuration number listed on the DEVICE DATA screen, which can be accessed in the SETUP/GENERAL/DEVICE DATA submenu. The **PIP Checklist** provides space to record this number before beginning the Performance Inspection Procedure (PIP).

The Device Configuration consists of ASCII characters. Character 0 is the rightmost character in the string.

19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0

Position	Name	Selection
19	Energy #1	0 = 150J 1 = 175J **2 = 200J** 3 = 225J 4 = 250J 5 = 275J 6 = 300J 7 = 325J 8 = 360J
18	Energy #2	0 = 150J 1 = 175J 2 = 200J 3 = 225J 4 = 250J 5 = 275J **6 = 300J** 7 = 325J 8 = 360J
17	Energy #3	0 = 150J 1 = 175J 2 = 200J 3 = 225J 4 = 250J 5 = 275J 6 = 300J 7 = 325J **8 = 360J**
16	CPR Time 1	0 = 60 sec 1 = 90 sec **2 = 120 sec** 3 = 180 sec 4 = 15 sec 5 = 30 sec 6 = 45 sec
15	CPR TIme 2	0 = 60 sec 1 = 90 sec **2 = 120 sec** 3 = 180 sec 4 = 15 sec 5 = 30 sec 6 = 45 sec
14	Init CPR Time	0 = 60 sec 1 = 90 sec 2 = 120 sec 3 = 180 sec 4 = Off 5 = Not used 6 = 15 sec 7 = 30 sec 8 = 45 sec
13	PreShock CPR Time	0 = Not used 1 = Not used 2 = Not used 3 = Not used 4 = Off 5 = Not used 6 = 15 sec 7 = 30 sec 8 = 45 sec

PIP – Device Configuration Table

Device Configuration (continued)

Position	Name	Selection
12	ECG Display Allowed/ ECG Display	ECG Display Allowed / ECG Display 0 = On / On 1 = On / Off 2 = Off / Off
11	Manual Access/ Analyze in Manual Mode	Manual Access / Analyze in Manual Mode 0 = On / On 1 = On / Off 2 = Off / Off
10	AED Monitoring/ AED Monitoring Repeat Time	AED Monitoring / AED Monitoring Repeat Time 0 = **Off** / **Off** 1 = On / 1 2 = On / 2 3 = On / 3 4 = On / 4 5 = On / Off
9	Reserved (for Audio Recording Equipped)	2 = Off
8	Voice Prompt Volume/ Service Alert/ Shock Tone	Voice Prompt / Service Alert / Shock Tone 0 = High / Off / Off 1 = High / Off / On 2 = High / On / Off 3 = High / On / On 4 = Medium / Off / Off 5 = Medium / Off / On 6 = Medium / On / Off 7 = Medium / On / On

PIP – Device Configuration Table

Device Configuration (continued)

Position	Name	Selection
7	Pulse Check/ Confirmation Analysis	Pulse Check / Confirmation Analysis 0 = Always / Off 1 = Always / On (non CONFIG A) 2 = After Every NSA / Off 3 = After Every NSA / On (non CONFIG A) 4 = Never / Off 5 = Never / On (non CONFIG A) 6 = Always 7 = After Every NSA 8 = After Second NSA (CONFIG A) 9 = Never
6	Shock Series/ Flex Energy	Shock Series / Flex Energy 0 = On / On 1 = On / Off 2 = Off / On 3 = Off / Off
5	Pulse Prompt/ Extended Prompt	Pulse Prompt / Extended Prompt 0 = Check Pluse / Off 1 = Check Breathing / Off 2 = Check Circulation / Off 3 = Open Airway / Off 4 = Check Pulse / On 5 = Check Breathing / On 6 = Check Circulation / On 7 = Open Airway / On
4	Auto Analyze/ Motion	Auto Analyze / Motion 0 = After 1st Shock / Off 1 = On / Off 2 = Off / Off 3 = After 1st Shock / On 4 = On / On 5 = Off / On

PIP – Device Configuration Table

Device Configuration (continued)

Position	Name	Selection
3	Delete After Send	0 = Off 1 = On
2	Init CPR	0 = Not Used (non CONFIG A) 1 = Off (CONFIG A) 2 = CPR First (CONFIG A) 3 = Analyze First (CONFIG A)
1	Spare	0
0	Spare	0

Note: “CONFIG A” is language dependent. For software version 2.2 release, languages Dutch, INT’L English, English (US), German, and Japanese are enabled with CONFIG A.

Test and Calibration Procedures

This section covers the Test and Calibration Procedures (TCP). Complete the relevant TCP to correct out-of-specification conditions detected during the **Performance Inspection Procedure** (PIP). **Note:** Any time the LIFEPAK 1000 defibrillator is calibrated, the device must successfully pass all portions of the closed-case **PIP** before being returned to active service. If a device exhibits any fault code or service wrench, contact Physio-Control; do not place it back in service.

TCP – Scope and Applicability

The TCP applies to the LIFEPAK 1000 defibrillator exclusively. You may perform the procedures outlined in this section in any order.

For display issues, perform the **LCD Screen Test**.

If energy levels are found to be out of tolerance during PIP testing, perform **Defibrillator Energy Calibration**, and **Device Service Log** check.

Refer to **TCP – Resource Requirements** for necessary equipment, test equipment verification, workstation power, and TCP personnel qualifications.

Refer to **TCP – Test Equipment Requirements** for a listing of test equipment, (including specifications) required to complete the TCP.

Note: All diagnostic codes in service log below 4000 are informational and can be cleared.

Note: Throughout the body of this TCP, the LIFEPAK 1000 defibrillator is referred to as the device.

TCP – Resource Requirements

This section describes the requirements for TCP equipment, TCP test equipment verification, TCP workstation power, and TCP personnel.

TCP – Equipment

To perform the TCP, you must use the equipment listed in the **TCP – Test Equipment Requirements** table. Although the table lists specific test equipment by manufacturer, test equipment with equivalent specifications may be substituted.

TCP – Test Equipment Verification

All test equipment used to perform the TCP must have a current calibration label. The calibration label must be issued by a certified calibration facility.

TCP – Workstation Power

The ac line power to the workstation must be connected to a grounded power source.

TCP – Personnel

Personnel who perform the TCP must be thoroughly familiar with the operation of the device and must meet at least one of the following requirements (or the equivalent):

- *Associate of Applied Science, with an emphasis in biomedical electronics*
- *Certificate of Technical Training, with an emphasis in biomedical electronics*
- *Equivalent biomedical electronics experience*

TCP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
Defibrillator Analyzer	**Output Power Measurement:** - Load resistance: 50 Ω ±1%non -inductive 160 W. - Range: 1000 J: 0-1000.0 J;100 J: 0-100.0J - Resolution: 0.1J - Accuracy: 1000 J Range: ± 2% of reading; 100 -1000 J: +/-2J 100 J Range: ± 2% of reading +/-0.1J	FLUKE QED-6 or equivalent*
Assembly Battery, Primary, 5/4C Cell, LIMNO2, LIFEPAK 1000		Physio-Control - P/N 3205379-002
Cable Assembly, Fast Patch, LIFEPAK 500		Physio-Control -P/N 3010493-004,-005
Oscilloscope (This is required if you are observing the defibrillator output waveform; otherwise, it is optional.)	Storage Scope 50 MHz, 50 ms/s minimum	Tektronix- TDS 410A or 430A or equivalent*

*Equivalent equipment is required to meet the specifications listed in the specifications column.

TCP – LCD Screen Test

L SOFTKEY R SOFTKEY

Perform this test when display problem is suspected or when LCD display and display cabling have been replaced.

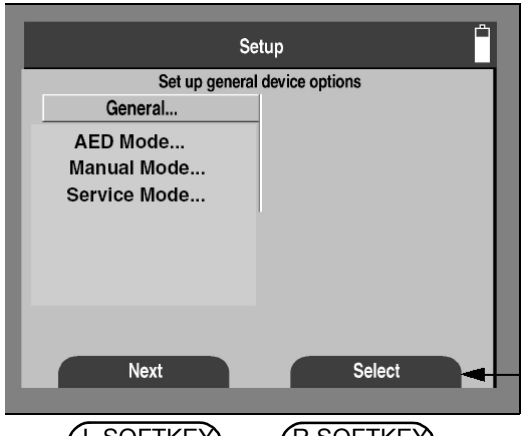
- Before beginning test, verify the **SERVICE INDICATOR** is covered by black rectangle, the **OK INDICATOR** is displayed, the **BATTERY CAPACITY INDICATOR** has one or more segments displayed.

To perform LCD SCREEN TEST:

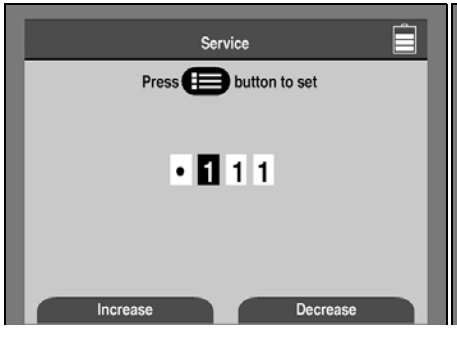
1. Place the device into **Service Mode** by following the steps below:
   a. Hold down **L SOFT KEY** and **R SOFT KEY** controls and turn on the device. Hold the controls until SETUP or SETUP MODE PASSWORD menu appears.

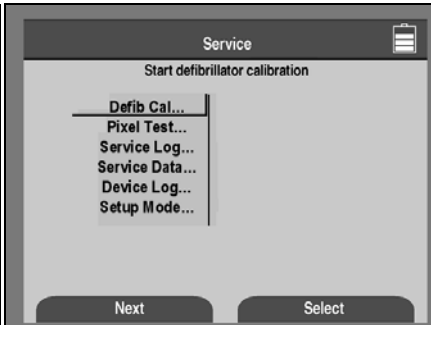
Note: For device software version 2.2 or greater with CONFIG A enabled, follow the on-screen directions and enter the 4 digit password (default is 0000) to enter SETUP MODE.

   b. Press the Next key until **Service Mode** is highlighted.
   c. Select **Service Mode** from the Setup menu.
   d. Select YES to enter Service Mode- Password screen.
   e. Enter 4 digit password (0000 default or 5433) to enter SERVICE MODE.



L SOFTKEY R SOFTKEY





TCP – LCD Screen Test

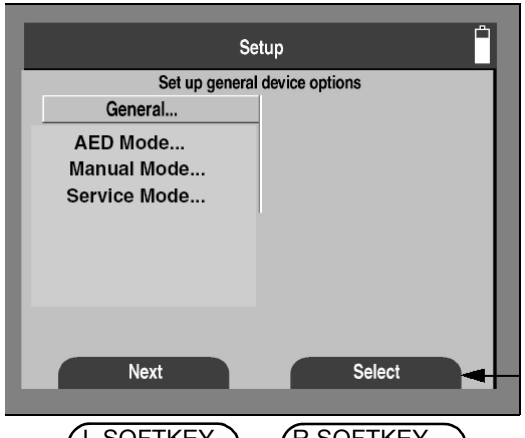
LCD Screen Test (continued)

Note: While entering Service Mode, if you wait longer than 5 seconds to make an entry, the screen will revert to the Setup screen. In this case restart from step b.

2. Select Pixel Test on Service menu.
3. Verify that there are no black stripes or white stripes indicating failed row and column on the LCD screen.
4. Press OK, repeat step 3, then press OK again.
5. Turn the device OFF.

TCP – Defibrillator Energy Calibration

L SOFTKEY R SOFTKEY



L SOFTKEY R SOFTKEY

DANGER

Shock hazard. Avoid contact with the energy meter. Dangerous voltages will be present on energy meter electrode plates/posts.

- Before beginning the test, verify that the **SERVICE INDICATOR** is covered by a black rectangle, the **OK INDICATOR** is displayed, and the **BATTERY CAPACITY INDICATOR** has one or more segments displayed.

Perform Defibrillator Energy Calibration when a component in the energy delivery path is replaced or if Defib. Energy Output is out of spec:

1. Place the device into **Service Mode** by following the steps below:
   a. Hold down **L SOFT KEY** and **R SOFT KEY** controls and turn on the device. Hold the controls until SETUP or SETUP MODE PASSWORD menu appears.

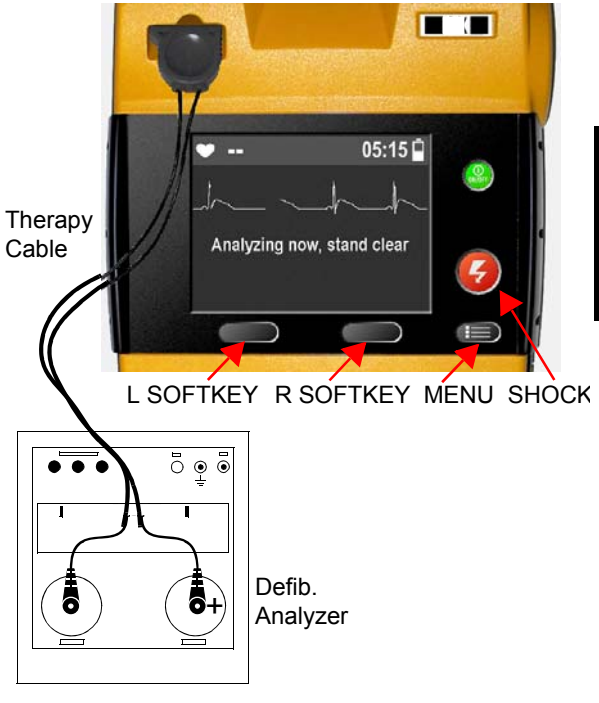
Note: For device software version 2.2 or greater with CONFIG A enabled, follow the on-screen directions and enter the 4 digit password (default is 0000) to enter SETUP MODE.

   b. Press the Next key until **Service Mode** is highlighted.
   c. Select **Service Mode** from the Setup menu.
   d. Select YES to enter **Service Mode- Password screen**.
   e. Enter 4 digit password (0000 default or 5433) to enter SERVICE MODE

Note: While entering Service Mode, if you wait longer than 5 seconds to make an entry, the screen will revert to the Setup screen. In this case restart from step b.

TCP – Defibrillator Energy Calibration

Defibrillator Energy Calibration (continued)



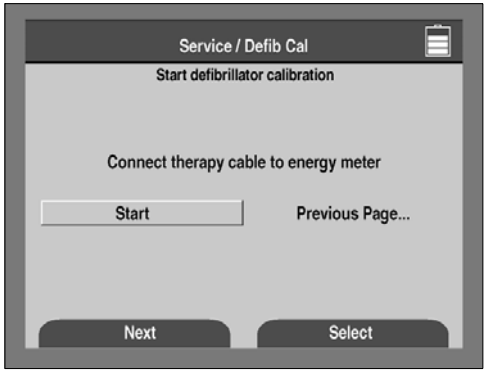
2. Connect the therapy cable between the device and Defibrillator Analyzer.
3. Set the Defibrillator Analyzer to the highest joule scale (1000J).
4. Turn Defibrillator Analyzer ON and press ENRG key to set the analyzer to Energy mode.

Note: The device will automatically calibrate at 2 energy levels: 100J and 360J.

5. Verify Defibrillator Analyzer's displayed energy value for each output is between min. and max, as shown in the table below

ENERGY-SETTING	ACCEPTABLE OUTPUT
100J	97.5 - 102.5 J
360 J	351.0 - 369.0J

6. Press **Select** on the device to Start defibrillator calibration routine.



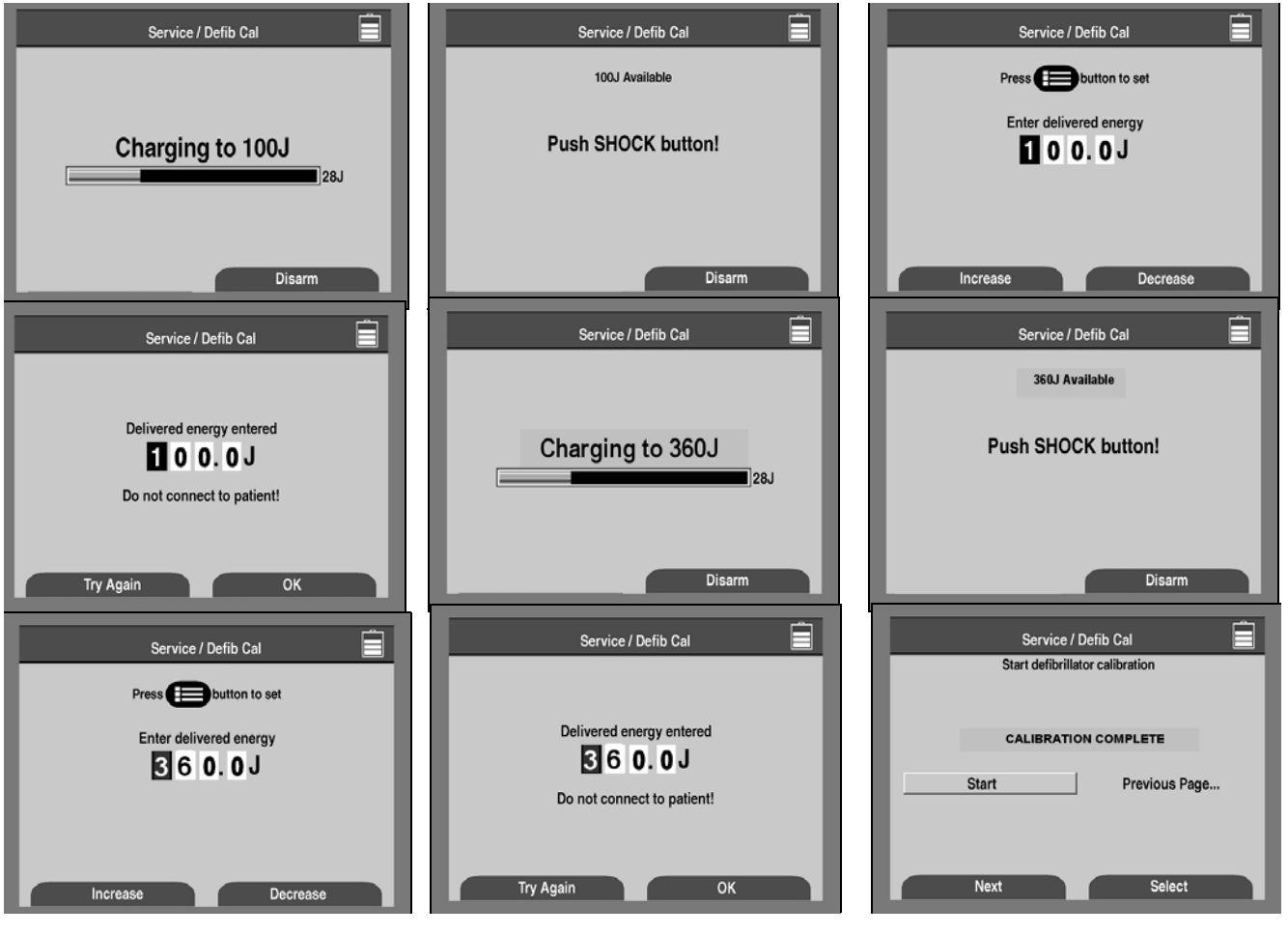
TCP – Defibrillator Energy Calibration

Defib. Energy Calibration Routine (continued)

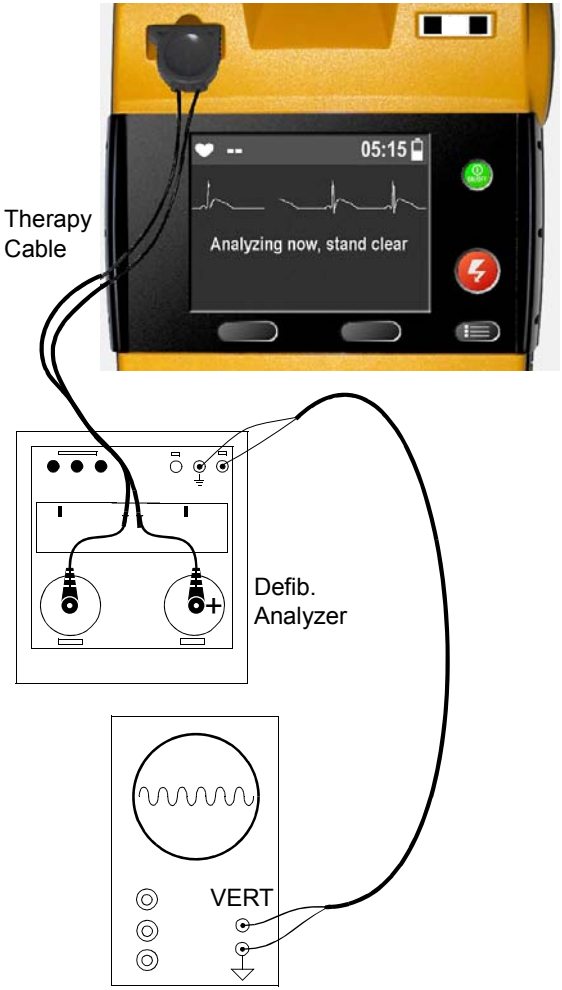
Note: The **Try Again** selection means that the operator can reenter the joule level value if an entry mistake is made.

Note: Use “Increase” and “Decrease” buttons on the device to adjust Energy value if needed.The adjusted value shall be within limits defined by the table in step 5

7. Follow the displayed calibration routine below.



TCP – Defibrillator Output Waveform (Optional test)



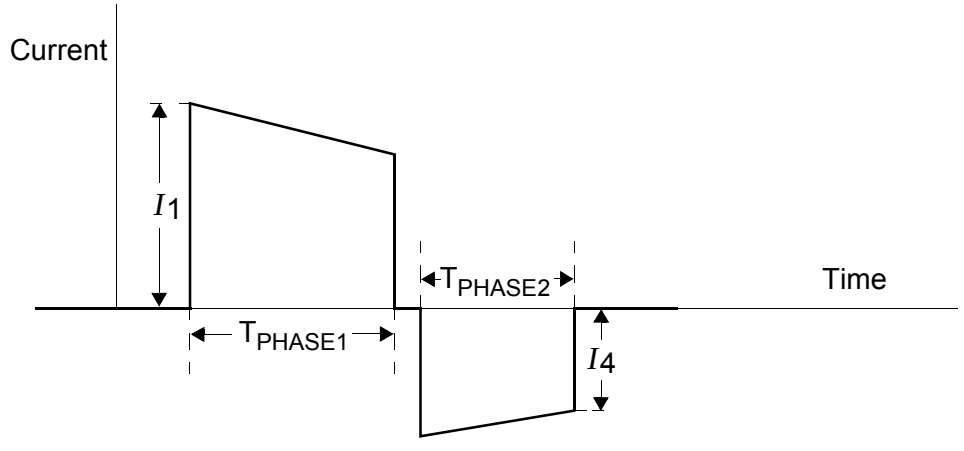
The **Defibrillator Output Waveform Test** is optional and is intended to aid in troubleshooting for failure symptoms in the defibrillator capacitor or the wave shaping inductor. Use a battery with at least one segment visible when you perform this procedure.

1. Connect the oscilloscope to the scope output connector of the defibrillator analyzer.
2. Set the oscilloscope to 0.5 V/div, 1 ms/div, + slope, store mode, and single sweep.

   Note: 1 V on the oscilloscope = 29 A defibrillator output current using the QED-6 energy meter. When using other energy meters, refer to the meter manufacturer's specifications.
3. Connect the therapy cable between the device and the Defibrillator Analyzer.
4. Set the Defibrillator Analyzer to **ENERGY** and highest joule scale (1000J).
5. Charge and discharge the device at 360J. (Refer to PIP Energy Verification 360J setup if device isn't configured for 360J)
6. Verify that the waveform meets the specifications shown on the following page.
7. Turn the device OFF. Disconnect all of the test equipment.

TCP – Defibrillator Output Waveform (Optional test)

Defib. Output Waverform
(continued)

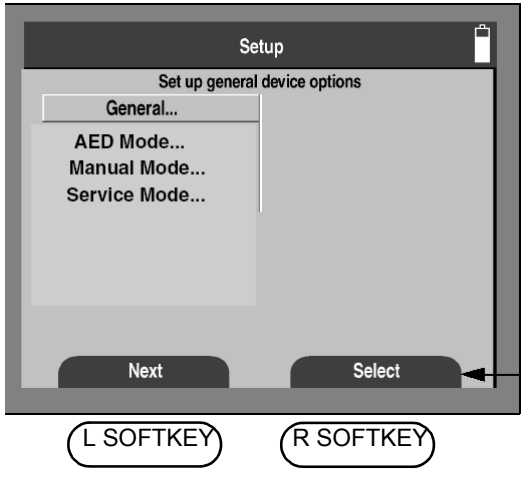


Patient Impedance (Ω)	I_1 (A)		T_1 (ms)		Tilt (%)	
	Min	Max	Min	Max	Min	Max
50	35	42	6.8	7.9	57	74.7

Note 1. Delivered waveform at 360 joules into given resistive load.
Note 2. Discharge polarity is APEX positive and STERNUM negative for Phase 1.

Note 3. $\text{Tilt} = \frac{(I_1 - |I_4|)}{I_1} X100$

TCP – Device Service Log



- Before beginning the test, verify that the **SERVICE INDICATOR** is covered by a black rectangle, the **OK INDICATOR** is displayed, and the **BATTERY CAPACITY INDICATOR** has one or more segments displayed.

Perform the device Service Log check any time the Service Wrench is displayed or when device is OFF and OK Indicator is OFF:

1. Place the device into **Service Mode** by following the steps below:
   a. Hold down **L SOFT KEY** and **R SOFT KEY** controls and turn on the device. Hold the controls until SETUP or SETUP MODE PASSWORD menu appears.

Note: For device software version 2.2 or greater with CONFIG A enabled, follow the on-screen directions and enter the 4 digit password (default is 0000) to enter SETUP MODE.

   b. Press the Next key until **Service Mode** is highlighted.
   c. Select **Service Mode** from the Setup menu.
   d. Select YES to enter **Service Mode- Password screen**.
   e. Enter 4 digit password (0000 default or 5433) to enter SERVICE MODE

Note: While entering Service Mode, if you wait longer than 5 seconds to make an entry, the screen will revert to the Setup screen. In this case restart from step b.

2. Select SERVICE LOG on the Service menu.

Verify that there are no diagnostic codes (except codes below 4000) in the Service Log. See “TCP – Scope and Applicability” on page 30.

3. Turn the device OFF.

LIFEPAK® 1000

Automated External Defibrillator (AED)
Performance Inspection Procedure Checklist

Part# _____ **Date** _____

Serial# _____ **Performed By** _____

Device Config: | | | | | | | | | | | | | | | | | | | | | **Department** _____

Type of PIP: **Post Repair** ☐ **Annual** ☐

Inspection		Pass	Failed	Comments
A	**Physical Inspection**			
	Record the result of physical inspection test.	❒	❒	
Testing				
1	**Battery Installation -Test**			
	Record the result of Battery Installation Test.	❒	❒	
2	**Power Up Initialization -Test**			
	Record the result of Power Up Initialization Test.	❒	❒	
3	**Service Alert Test / Audio- Voice Prompt Test**			
	Record the result of Service Alert Test and Audio- Voice Prompt Test.	❒	❒	
4	**Defibrillator Energy Output / Charge time Tests/Buttons and Keys Test/Dump test**			
	Energy Level at 100 J — Range 95- 105 J	❒	❒	
	Energy Level at 360 J — Range 342 - 378 J	❒	❒	
	Record that device completes charge time in less than 14 seconds.	❒	❒	
	Record that all contorls on the Device are functioning property.	❒	❒	
	Defibrillator Energy Dump Test			
	Record that no service wrench result on the device.	❒	❒	
5	**Date and Time / LCD Contrast / Full Monthly Auto Test**			
	Record the result of Time and Date, LCD Contrast and Full Monthly Test.	❒	❒	
6	**Electrode Impedance Test**			
	Record the result of Electrode Impedance Test. — 355Ω - Check Electrodes; 246Ω - Stand Clear; 5Ω - Check Electrodes	❒	❒	
7	**Warm Boot Detection Test**			
	Record the result of Warm Boot Detection Test., **range 5 - 49 seconds**	❒	❒	
8	**3 ECG Leads Characteristic Test** (Note: Complete if the Device is equipped with 3 Lead ECG option)			N/A
	a - Record the result of ECG Lead Characteristic Test. — 10Hz Sinewave, 1mv = 10mm	❒	❒	❒
	b - Record the result of ECG BPM Test. — ECG 120 BPM = 120 ± 3 BPM	❒	❒	❒
	c - Confirm "Connect ECG Leads" message.	❒	❒	❒
9	**Therapy ECG Characteristic Test**			
	Record the result of Therapy ECG Characteristic Test. — QRS Waveform @120 BPM = 11mm	❒	❒	

10	**Leakage Current Tests**		Pass	Failed	Comments
	a - Record the result of Therapy ECG Leakage current Test.	0 µA to 9 µA	❒	❒	
	b - Record the result of 3 Leads ECG Leakage current Test. (if option)	0 µA to 9 µA	❒	❒	❒

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